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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,180	01/20/2004	Jeffrey A. Hubbell	NOVCEL.3CPDDVC	2061
36647	7590	06/28/2005	EXAMINER	
NOVOCELL, INC. 31 TECHNOLOGY DRIVE SUITE 100 IRVINE, CA 92618			BERMAN, SUSAN W	
			ART UNIT	PAPER NUMBER
			1711	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/761,180

Applicant(s)

HUBBELL ET AL.

Examiner

Susan W. Berman

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 129-138 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 129-138 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 01/04.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 129-138 are rejected under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al (5,700,848 or 5,705,270 or 5,846,530). See the Abstract and Examples 16-18 in US '848. Soon-Shiong teaches that the disclosed macrocapsules may contain cells that are encapsulated within microcapsules (column 9, lines 22-24, Example 26). With respect to claim 130, Soon-Shiong teaches poly(ethylene glycol), poly(amino acids), polysaccharides and proteins. Coextrusion is taught in Examples 16, 20 and 26. An accelerator to increase the rate of polymerization is taught in column 7, lines 37-49. With respect to claim 131, Soon-Shiong et al do not teach PEG tetraacrylate. However, the claim, as written, does not limit the macromer to being PEG tetraacrylate, it merely states that the PEG in the Markush group is PEG tetraacrylate.

Claims 1, 129-135 and 137-138 are rejected under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al (5,545,423 or 5,759,578 or 5,788,988 or 5,879,709). See the Abstract, column 7, line 43, to column 8, line 14, column 8, line 37, to column 9, line 14, column 11, line 64, to column 12, line 32, and Examples 5, 6 and 7 in US '423. Soon-Shiong teaches a method of microencapsulating cells such as islets and then encapsulating the microspheres in macrocapsules. With respect to claim 130, Soon-Shiong teaches polymerizable alginate, water-soluble poly(alkylene glycol), poly(amino acids), polysaccharides and proteins. An accelerator to increase the rate of polymerization is taught in column 10, lines 36-48. With respect to claim 131, Soon-Shiong et al do not teach PEG tetraacrylate. However, the claim, as

Art Unit: 1711

written, does not limit the macromer to being PEG tetraacrylate, it merely states that the PEG in the Markush group is PEG tetraacrylate. With respect to claim 132 or 133, the claims, as written, do not limit the method of claim 3 to selection of polysaccharides or proteins from the Markush group set forth.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 129-138 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of U.S. Patent No. 5,529,914. Although the conflicting claims are not identical, they are not patentably distinct from each other because the biological cells recited in the claims of US '914 include islet cells (see claim 20) and cells first encapsulated in microcapsules (see claim 2).

Claims 1 and 129-138 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,258,870. Although the conflicting claims are not identical, they are not patentably distinct from each other because the biological cells recited in the claims of US '914 include islet cells (see claim 15) and cells first encapsulated in microcapsules (see claim 50).

Art Unit: 1711

Claims 1 and 129-138 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,858,746. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US '746 recite the same steps for encapsulating mammalian cells using initiation by light. See claims 1, 16, 18 and 31.

Claims 1 and 129-138 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,801,033. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US '033 recite the same steps for encapsulating mammalian cells as set forth in the instant claims. See claims 1, 2, 11 and 12.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W. Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1711

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Susan W Berman
Primary Examiner
Art Unit 1711

SB
6/25/05